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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,631	12/31/2003	Heinz-Werner Kleemann	DEAV2002/0094 US CNT	8300

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EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/749,631	Applicant(s) KLEEMANN ET AL.	
	Examiner Rebecca L. Anderson	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 7-19,21-32 and 34-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,20 and 33 is/are rejected.
- 7) ☒ Claim(s) 1-6,20 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>Feb 9, 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-48 are currently pending in the instant application. Claims 7-19, 21-32 and 34-48 are withdrawn from consideration as being for non-elected subject matter, claims 1, 2, 5, 6, 20 and 33 are rejected and claims 1-6, 20 and 33 are objected.

Election/Restrictions

Applicant's election of Group I, claims 1 to 6, 20 and 33 and the further election of the compound of 3-guanidineocarbonyl-1-(7-methyl-7H-pyrrolo[2,3-d]pyrimidin-4-yl) in the reply filed on 22 November 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Therefore, as stated on pages 3 and 4 of the restriction requirement, **the elected invention for search and examination is:**

The products of the formula (I) wherein **R1, R2, R3,n, Ra, Rb** and **R4** are as found in claim 1 and **Ar** is 7H-pyrrolo-[2,3-d]-pyrimidine, which may be linked via any of its positions and which is substituted in at least one of its positions by alkyl having 1, 2, 3, 4, 5 or 6 carbon atoms, halogen, nitro, NRaRb, alkylcarbonylamino having 1,2,3 or 4 carbon atoms, hydroxyl, alkoxy having 1,2,3,4,5 or 6 carbon atoms, S(O)_nR4, Co2H, alkoxycarbonyl having 1, 2, 3, 4, 5 or 6 carbon atoms, alkylcarbonyl having 1,2,3,4,5 or 6 carbon atoms, CONRaRb, CN, polyfluoroalkyl having 1,2,3 or 4 carbon atoms, polyfluoroalkoxy having 1,2 or 3 carbon atoms or SO3H, or a racemic mixture, enantiomer, diastereomer, or tautomer of such compound, or a mixture thereof, or a

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pharmaceutically acceptable salt of such compound, racemic mixture, enantiomer, diastereomer, tautomer, or mixture.

The remaining subject matter of claims 1-6, 20 and 33 that is not drawn to the above elected invention and the subject matter of claims 7-19, 21-32 and 34-48 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining compounds which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn by means of a restriction requirement within the claims are, for example, the compounds of the formula (I) wherein AR is for a 9 to 10 membered bicyclic heteroaryl other than 7H-pyrrolo-[2,3-d]-pyrimidine, for example, wherein Ar is a quinoline, isoquinoline, or quinazoline.

The above mentioned withdrawn compounds, which are withdrawn from consideration as being for nonelected subject matter, differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds differ from those of the elected invention, such as by quinoline, isoquinoline, or quinazoline, etc. which are chemically recognized to differ in structure and function. This recognized chemical diversity of the compounds can be seen by the various classification of these compounds in the U.S. classification system, i.e. class 544 subclass (283)+ quinazoline, class 546 subclass (152)+ quinoline, class 546 subclass (139)+ isoquinoline, etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and

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composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter.

These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the compound elected and are therefor withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper and is therefore maintained.

Claim Objections

Claims 1-6, 20 and 33 are objected to as containing non-elected subject matter. Claims 1-6, 20 and 33 presented drawn solely to the elected invention identified supra wherein Ar is 7H-pyrrolo-[2,3-d]-pyrimidine would overcome this objection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5, 6, 20 and 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 7, 21 and 34 of copending Application No. 10/749620 (see US Pre-Grant Publication 2005/0026989). Although the conflicting claims are not identical, they are not patentably distinct from each other because applicants' elected invention of instant claims 1, 2, 5, 6, 20 and 33 are claiming compounds wherein Ar is a 7H-pyrrolo-[2,3-d]-pyrimidine, diagnostic agents and pharmaceutical compositions.

Conflicting claims 1, 2, 5, 6, 7, 21 and 34 are claiming compounds (conflicting claims 1 and 2), pharmaceutical compositions (conflicting claims 6 and 7) and diagnostic agents (conflicting claims 20 and 33) of the formula (I) wherein the positions equivalents to applicants R1, R2 and R3 are identical. However, the conflicting claims have the positions equivalent to the unsubstituted positions of applicants indole as

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hydrogen, alkyl having 1, 2, 3, 4, 5, or 6 carbon atoms, halogen, NraRb or polyfluoroalkyl having 1, 2, 3, or 4 carbon atoms (conflicting R2) and as hydrogen or halogen (conflicting R5). While the conflicting claims have Ar as a 9 or a 10 membered bicyclic heteroaryl having one, two or three nitrogen atoms in conflicting claim 1, a preference is found towards applicants' elected invention in conflicting claim 2 wherein Ar can be 7H-pyrrolo-[2,3-d]-pyrimidine. Preferences to conflicting R2 and R5 as hydrogen can be seen in conflicting claim 5 wherein the discloses species have R2 and R5 as hydrogen.

The difference between the claims at issue and the conflicting claims is that the compounds claimed in US application No. 10/749,630 generically overlap with applicants' instantly claimed elected invention. However, preferences are found in the conflicting claims for Ar as 7H-pyrrolo-[2,3-d]-pyrimidine and R2 and R5 as hydrogen.

Therefore, it would have been obvious to one of ordinary skill in the art, when faced with the conflicting claims of 10/749630 to prepare applicants' instantly claimed elected invention as the conflicting claims generically overlap with applicants' instantly claimed elected invention and have preferences towards Ar as 7H-pyrrolo-[2,3-d]-pyrimidine and R2 and R5 as hydrogen. The motivation would be the expectation of preparing additional products useful as diagnostic agents and pharmaceutical compositions for the treatment of, for example, metastasis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Non-elected Subject Matter Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

The non-elected subject matter of claims 1, 2, 5, 6, 20 and 33 is rejected under 35 U.S.C. 103(a) as being obvious over LANG et al., US Patent No. 5,852,046.

Determining the scope and contents of the prior art

US Patent No. 5,852,046 discloses benzo-fused heterocyclic compounds having a 5-membered ring and their use as diagnostic agents and medicaments on column 1, lines 15-17. The benzo-fused heterocyclic compounds having a 5-membered ring are of the formula I wherein X can be N or CR(6); Y can be oxygen, S or NR(7); A and B together are a bond or are both hydrogen; one of the substituents R(1) to R(7) is -CO-N=C(NH₂)₂; the other respective substituents R(1) to R(6) are such as H or (C1-6)alkyl; n is zero to 10; R(7) can be hydrogen or R(8)-C_nH_{2n}; and R(8) can be hydrogen, (C2-6)alkenyl, phenyl, 1- or 2-naphthyl, pyridyl, quinolyl or isoquinolyl (columns 1 and 2). Preferences towards the non-elected subject matter of applicants' instant invention are

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found in the preferences wherein Y is NR(7) (column 2, line 29); one of the substituents R(1) to R(6) is CO-N=C(NH₂)₂; A and B are a bond (column 2, line 30); n is zero to 4 (column 2, line 41); R8 can be quinolyl or isoquinolyl (column 2, line 63). Further preferences to compounds which are positional isomers of the non-elected subject matter of the claimed invention are found in preferred embodiments on column 3 wherein X is CR(6); Y is NR(7); A and B together can form a bond; R(1) is –CO-N=C(NH₂)₂; n can be zero; R(8) can be quinolyl or isoquinolyl; and R97) can be R(8)-CnH_{2n}. Further preferences are found on columns 3 and 4 wherein R(8) can be quinolyl or isoquinolyl and can be substituted by 1 to 3 substituents chosen from the group consisting of F, Cl, Br, I, CF₃, etc.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the non-elected subject matter of the claims at issue is that the prior art does not specifically disclose a specific compound of the instantly claimed formula (I). However, the prior art discloses the compounds of the formula (I), which generically overlap with applicants' instantly claimed non-elected products and generically overlaps with positional isomers of applicant's instantly claimed non-elected products. Furthermore, the prior art does disclose preferences towards applicants' instantly claimed non-elected products and preferences towards positional isomers of applicants' instantly claimed non-elected products which provides direction and motivation to prepare the non-elected subject matter of applicants' instantly claimed invention.

Resolving the level of ordinary skill in the pertinent art

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the non-elected compounds within applicants instant compound of formula I when faced with the prior art of Lang et al. since the prior art discloses products, diagnostic agents and pharmaceutical compositions which generically overlap with the non-elected subject matter of the claimed invention and positional isomers thereof and provides direction towards applicants' non-elected subject matter of the instant claims within the preferred embodiments. The motivation would be to the expectation of preparing more biologically active benzo-fused heterocyclic compounds useful as diagnostic agents and as pharmaceutical compositions for the treatment of conditions such as atherosclerosis. Furthermore, nothing unobvious is seen in substituting the claimed isomer for the structurally similar isomer, as taught by LANG et al. since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950).

Conclusion

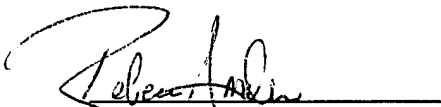
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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